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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,485	03/03/2006	Eishin Kato	80110(302725)	9937
21874 7590 02/23/2011 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
MI, QIUWEN				
ART UNIT		PAPER NUMBER		
1655				
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02/23/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/570,485

Applicant(s)

KATO ET AL.

Examiner

QIUWEN MI

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-9,16,17,19 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-9,16,17,19 and 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/3/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/2011 has been entered.

Applicant's amendment in the reply filed on 1/27/2011 is acknowledged, with newly added claims 21-31. Claims 2-4, 10-15, 18, and 20 are cancelled. Claims 1, 5-9, 16, 17, 19, and 21-31 are pending. Claim 6 is withdrawn. **Claims 1, 5, 7-9, 16, 17, 19, and 21-31 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/27/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Claim 7 recites "A vegetable extract comprising Gnetum according to claim 5 being added to vegetable extract". The recitation is very confusing, as Gnetum itself is a vegetable, and it is not clear whether the 50% ethanol extract of Gnetum is the vegetable extract or the 50% ethanol extract of Gnetum has to be added and mixed with another vegetable extract.

Therefore, the metes and bounds of claims are rendered vague and indefinite. The lack of clarity renders the claims very confusing and ambiguous since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7-9, 16, 17, and 19 remain rejected, and claim 21-31 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Boralle et al (Oligostibenoids from Gnetum

venosum, *Phytochemistry*, 34 (5): 1403-1407, 1993), in view of Berry (Cyclopropene fatty acids in *Gnetum gnemon* (L.) seeds and leaves, *Journal of the Science of Food and Agriculture*, (1980) Vol. 31, No. 7, pp. 657-662), and further in view of Iliya et al (Iliya et al, Stilbene derivatives from two species of Gnetaceae, *Chem. Pharm. Bull.* 50 (6) 796-801 (2002)), and Qi (Qi, Optimum for extraction processing of stilbene glucoside from *Polygonum multiflorum*, *Zhongcaoyao* (2002), 33(7), 609-611).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/27/2010, repeated below, slightly altered to take into consideration Applicant's amendment filed on 12/27/2010. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Boralle et al teach extracting the seeds of *Gnetum venosum* by exhaustive percolation (thus soaking) with EtOH (thus a solid-liquid mixture, an organic solvent, a polar organic solvent, thus soaking and aging, hydrolyzing by glucosidase in the seeds). The solution was evaporated (thus solid content is removed or filtering, the solvent are distilled away, thus the limitation of claim 27 is met) and the residue partitioned between CHCl_3 , and MeOH. The solvents were evaporated. The residue of the CHCl_3 solution was fractionated first by CC and finally by TLC. All compounds were purified by HPLC (see title; page 1407, 1st column, 5th paragraph). Boralle et al also teach *Gnetum venosum* contains, besides the stilbenes resveratrol and reponitigentin, oxidative stilbene oligomers such as the dimer gnetic C and the tremers gnetic E, gnetic J and gnetic K (see Abstract). It is noted that since Boralle et al do not specify the percolation temperature, it is assumed that the percolation is performed under room temperature, which is below 70 degree C. Even if the extraction is performed under EtOH reflux,

since the boiling point of ethanol is 78.4 degree C, it meets the claim limitation of “below about 70 degree C”.

Boralle et al do not explicitly teach using 15-80% EtOH or 50% EtOH to extract *Gnetum gnemon* seeds, nor do Boralle et al teach mixing *Gnetum* extract to vegetable extract, or an aged *Gnetum* extract of more than 12 h, neither do Boralle et al teach the limitations in claims 21-31.

Iliya et al teach the family of Gnetaceae is known to contain stilbenoids. The leaves and the fruits are used as food in many parts of tropics. Five new stilbenoids isolated from two species of Gnetaceae. Gnemonoils A and B were obtained from the root of *Gnetum gnemon*. Gnemonol C, gnemonoside E and gnetal were isolated from both species (page 796, 1st column, 1st paragraph).

Berry teaches seed kernels of *Gnetum gnemon* (thus *Emping belinjo*), eaten after boiling or roasting the nuts (see Abstract). Berry teaches that nuts are starchy, astringent and rather bitter in taste that persists even after cooking. The kernels are eaten after removing the shell (thus removing a pericarp and a seed coat leaving an endosperm portion of the seed, thus the limitation of claim 23 is met) from the roasted or boiled nuts. They are mashed, moulded into cakes, biscuits or pounded flat into ‘keropok’ (crisps) which are dried in the sun (thus not higher than 100 degree C without converting starch in the seed into alpha-starch, thus not convert starch inside the seeds into alpha-starch, thus claims 21 and 22 are met) and deep-fried in oil prior to consumption (page 44, 1st paragraph). Berry also teaches the young leaves of the plant are consumed as vegetable (page 44, 2nd paragraph). Berry teaches the oven-dried nuts were shelled manually, and the pulverized kernels were extracted with petroleum ether (bp 40-60 degree C)

in a soxhlet apparatus for 16 h. The extract, after filtration, was evaporated on a rotary evaporator at 45 degree C under reduced pressure (page 658, 2nd paragraph).

Qi teaches stilbene glucoside was extracted from *Polygonum multiflorum* with 6.0-fold 50% ethanol (thus the limitation of claim 26 is met) by refluxing for 30 min. The effect of extraction on stilbene glucoside level was studied by HPLC. The content of stilbene glucoside in the extract was affected by extractant concentration and extraction time, preferably extractant concentration (see Abstract, the rejection is based on the Abstract, full translation was attached in the last office action).

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use ethanol (thus polar solvent) to extract stilbene from the seeds or seeds containing material from *Gnetum gnemon* since Boralle et al teach that it is from the seeds of the same genus *Gnetum*, stilbene was isolated. Further more, Iliya et al teach the family of Gnetaceae is known to contain stilbenoids, and stilbene was isolated from the root of claimed species *Gnetum gnemon*. Therefore, an artisan of ordinary skill at the time of the invention would have had a reasonably expected that the seeds or seed containing material of *Gnetum gnemon* has the sought properties, which are stilbenes, namely gnetin C, gnetonocide A and Gnetonocide D, and it is deemed that the claimed material stilbenes would necessarily have the claim designated antimicrobial and/or antioxidative function.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to boil the *Gnetum gnemon* kernels (the same as seeds) and leaves (thus mixing with vegetable extract) together (thus a polar extract water) and then to consume since Berry teaches both the kernel and leaves can be eaten.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use 50% ethanol to extract stilbenoid since Qi teaches using 50% ethanol to extract stilbene glycoside (thus a stilbenoid) and the content of stilbene glucoside in the extract was affected by extractant concentration.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to filtrate after ethanol extraction as evidenced by Berry, filtration step is a common practice in solvent extraction.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to dry the plant parts under the sun or in shade after plant collection (thus less than 100 degree C, thus without converting starch in the seed into alpha-starch) and before solvent extraction.

Since all of the references teach using plant materials from genus *Gnetum*, one of ordinary skill in the art would have been motivated to make the modifications and combine the references together.

Regarding to the claimed soaking temperature of 30-60 degree C in claim 28, the weights of seeds and solvent, or the extraction time in claims 29-31, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235

(CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the extraction conditions in claims 28-31, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal extraction conditions, which would have been routinely determined and optimized in the pharmaceutical art. For instance, a larger amount of solvent and a higher temperature will reduce the extraction time, and increase the extraction efficacy.

The MPEP states the following: "[E]ven though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself. The

patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process...The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product" (see MPEP 2113 [R-1]).

Since the references teach extracting the claimed material Gnetum seeds with the claimed solvent ethanol, it is deemed that the extracts would intrinsically have the claimed absorption spectrum and R_f value.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as cosmetic or seasoning products. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "The claimed invention, however, differs from the combination of the cited art at least in the utilization of the aging which converts the stilbene glucoside into the aglycon by hydrolysis without addition of some glucosidases. The aging means action (for example, hydrolysis) of glucosidase in endosperms. The applicants found out the phenomenon

given only gnemonoside A by extraction of Emping Belinjo produced by heat-processing of endosperms (Comparison I). The enzyme reaction (hydrolysis) is affected the concentration of polar organic solvent, soak (extract) temperature and time. On the other hand, skilled artisans who do not notice this phenomenon make the enzyme reaction inhibited and inactivated by use of single polar organic solvent and heat reflux (page 5, last paragraph bridging page 6).

This is not found persuasive. The claims do not mention anything about converting the stilbene glucoside into the aglycon by hydrolysis without addition of some glucosidases, neither do the claims mention about the only product of emping belinjo extraction is gnemonoside A.

Applicant argues that “The applicants investigated extraction and aging of endosperms under various conditions to discover the aqueous extractant containing the polar organic solvent concentration in the range of 15% to 80% and soak temperature below about 70°C. The extractant ranging in the concentration from 40% to 60% resulted in gnetin C as major composition in contrast to gnemonoside A. Thus the composition ratio of gnetin C in the extract has been controlled. The extract containing antimicrobial gnetin C brings about extension of the shelf life of foods and cosmetics in addition to improvement of flavor of vegetable extract” (page 6, 2nd paragraph).

This is not found persuasive. The claims do not recite the concentration or relative ratio of gnetin C and gnemonoside A.

Applicant argues that “As noted above, an artisan of ordinary skill cannot expect from Boralle, Berry, Illiya and Qi that such a glucosidase exists in the endosperms, not to mention making antibacterial and antioxidative gnetin C from gnemonoside A under appropriate

conditions which are the aqueous extractant containing the polar organic solvent concentration in the range of 15% to 80% and soak temperature below about 70°C" (page 6, 3rd paragraph).

This is not found persuasive. The claims do not mention anything about glucosidase in the endosperms, neither do the claims mention anything about gnenonoside A.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655